August 11, 2014

Dr. Louis Jacques
Senior Vice President and Chief Clinical Officer
ADVI
1050 K Street, N.W.; Suite 340
Washington, D.C. 20001

Dear Dr. Jacques:

Thank you for appearing before the Subcommittee on Health on July 22, 2014, to testify at the hearing entitled "21st Century Cures: Examining Barriers to Ongoing Evidence Development and Communication."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on August 25, 2014. Your responses should be mailed to Jessica Wilkerson, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Jessica.wilkerson@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

Attachment 1—Additional Questions for the Record

The Honorable Joseph R. Pitts

1. In previous hearings and meetings, some innovators have suggested that FDA approval is not the last hurdle or barrier to get over, and sometimes CMS will require additional studies to satisfy coverage requirements after FDA approval. While I am not suggesting these studies are not important, they do increase the cost of development on the company. For medical device manufacturers, where the typical innovator is small to medium sized, such costs – if unforeseen – can threaten their viability. Are there recommendations you might have with regards to this process that might help change the predictability of the CMS coverage process?

2. The most recent SGR patch legislation, otherwise known as the Protecting Patient Access to Medicare Act of 2014, created a requirement for product specific coding for molecular or advanced diagnostic tests. Such coding has been generally viewed as a positive step toward incentivizing new testing platforms. You state in your testimony that venture capitalists have suggested a similar paradigm could be applied to other innovative technologies. Can you explain in detail how such a paradigm might look? Please include as much specific detail as possible.

3. You state that CMS needs unambiguous authority to review clinical trials when claims related to these trials will be submitted for Medicare payment. In what ways is CMS authority in this respect limited and how does it impact the search for cures?

4. You state in your testimony that Local Coverage Determinations (LDCs) could be revised to permit them to be used by the Secretary within the scope of the Medicare program. Can you explain the barriers to such use and why making a change like this might help?